UNITED STATES PATENT AND TRADEMARK OFFICE

1

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,444	09/30/2003	Matthias Gicse	APB-2	7837

7590 07/14/2006

O. M. (SAM) ZAGHMOUT PH.D
BIO INTELLECTUAL PROPERTY SERV ICE (BIO IPS)
8509 KERNON CT.
LORTON, VA 22079

EXAMINER
HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,444	GIESE, MATTHIAS	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the c v r sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 9 June 2006.

Election/Restriction

Applicant elects Group I, claims 1-14, 24, and 25, with traverse. The traversal is on the grounds that that there is no search burden in examining the different Groups of inventions together. Applicant's traversal is partially persuasive. Groups I and II have been rejoined since they are both drawn to nucleic acids and vectors. Group III, however, remains patentably distinct for reasons stated in the prior Office Action.

The restriction of Group III is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-25 are pending. Claims 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9 June 2006.

Claims 1-20, 24, and 25 are examined.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1 defines EAV differently from the specification. Claim 1 recites "equine arterivirus" whereas the specification refers to "equine arteritis virus."

Claims 3 and 15 are indefinite in their recitation of "ORF1a, ORF 1b, ORF 3, ORF 4, ORF6," which is not identified by any SEQ ID NO.

Claims 2, 4-14, and 16-20 are rejected for depending from indefinite base claims.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 15-19, 24 and 25 are rejected under 35 U.S.C. §102(b) as being anticipated by Tobiasch *et al.* (2001).

The instant claims are directed to a EAV vaccine composition that induces a cellular immune response, comprising an open reading frame nucleic acid (ORF)2, ORF5, and/or ORF7 of EAV.

Tobiasch *et al.* teaches that EAV is a member of the *Arteriviridae* family that includes lactate dehydrogenase-elevating virus (LDV), porcine reproductive and respiratory syndrome virus (PRRSV), and simian hemorrhagic fever virus (SHFV). Specifially, Tobiasch *et al.* teaches prevention of EAV in horses by DNA vaccination. The cDNA sequence of ORF3, ORF4, ORF5, and ORF7 (Table 1) were molecularly

cloned into the corresponding sites of expression vectors pCR3.1, pDisplay, and/or pcDNA3.1/HisC. See Abstract and on page 189-190, Molecular Cloning of Viral cDNA and Preparation of Plasmid DNA. The vaccine composition comprises one or several vectors, each comprising the aforementioned individual EAV ORF. See page 193, DNA Vaccination of Mice with Vector Construct Expressing Viral ORFs 5 and 7. The vaccine composition further comprises PBS (p.191, DNA Vaccination of Animals), which is a pharmaceutically acceptable carrier or excipient. Thus, the instant invention is anticipated by Tobiasch *et al.*

Claims 1, 2, 4-10, 12, 14-19, 24 and 25 are rejected under 35 U.S.C. §102(a) as being anticipated by Giese *et al.* (2002).

The instant invention is further limited to the specific embodiment of a vaccine composition comprising vectors of ORF2, ORF5, ORF7, and equine interleukin 2 (IL-2).

Giese *et al.* teaches teaches that EAV is a member of the *Arteriviridae* family. Specifially, Giese *et al.* teaches prevention of EAV in horses by DNA vaccination of multiple expression vectors, each encoding the ORF2, ORF5, and ORF7, in combination with equine IL-2. See Abstract. The viral cDNA of the ORFs are cloned into the mammalian expression vectors pCR3.1, pcDNA3.1, pcDNA3.1/His, pDisplay. See p.160, Construction of Plasmids Expressing EAV ORF 2, 5, and 7 Genes. Prior to injection of horses were with a gene gun, the vector is encapsulated into cationic liposomes by adding DOTAP Liposomal or Lipfection buffer to DNA. See p.163, ¶1.

Thus, the instant invention is anticipated by Giese *et al.*

Claim rejection – 35 USC § 102 / 103

Claims 1, 3-8, 10, 13, 15-20, 24 and 25 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Tobiasch *et al.* Tobiasch *et al.* discloses cDNA and amino acid sequences from current GenBank, EMBL, and SwissProt database sequence entries. Given the general molecular method of cloning the EAV ORFs into the same expression vectors, the vector preparations disclosed in Tobiasch *et al.* meet the limitations of the claims directed to nucleic acids and vectors. Since the claimed ORF sequences are the same as the nucleotide sequences published in GenBank – SEQ ID NO:2 matching nucleotide 9790-10473 of accession number AR013959; SEQ ID NO:5 matching nucleotide 11113-11879 of accession numbers AR013959 and A45589; and SEQ ID NO:7 matching nucleotide 12279-12611 of accession numbers A45589 and A58849 – and Tobiash *et al.* discloses GenBank database, the claimed sequences must be inherently disclosed in Tobiash *et al.* Where applicant claims a composition in terms of a characteristic not explicitly disclosed by the reference, a 102/103 rejection is proper (MPEP §2112).

Patent owner's burden under the circumstances presented herein was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

> Where, as here, the claimed and prior ad products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior ad products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. §102, on 'prima facie obviousness' under 35 U.S.C. §103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior ad products (footnote omitted).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-8, 10, 11, 15-19, 24 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tobiasch *et al.* in view of Krieg *et al.* (1998).

The relevance of Tobiasch *et al.* is set forth above. Tobiasch *et al.* does not disclose any adjuvant in the vaccine composition.

Krieg *et al.* suggests unmethylated CpG dinucleotides as adjuvant for DNA vaccines. Specifically, Krieg *et al.* discloses that CpG motifs can be added deliberately to DNA or conventional protein vaccines to enhance the Th1 immune response. See Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the DNA vaccine composition of Tobiasch *et al.* by adding CpG dinuleotides as taught by Krieg *et al.* The skilled artisan would have been motivated to do so to exert an essential endogenous adjuvant activity for the EAV ORF vaccines and to increase the efficacy of the EAV vaccine compositions. There would have been a reasonable expectation of success, given that CpG DNA can directly activate both B cells and monocytic cells including macrophages and dentritic cells (See Figure 1), as taught by Krieg *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowable.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP §714.02 and §2163.06.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Humphrey, Ph.D.
3 July 2006